K020739

JUN 0 3 2002

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Summary of Safety and Effectiveness

Submitter:	BCI, Inc.
Address:	N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	March 1, 2002
Proprietary Name:	BCI 3178 Pediatric Pulse Oximetry Sensor
Common/Classification Name:	Pulse Oximeter Sensor
Predicate Devices:	BCI 3044 Reusable Pulse Oximetry Sensor (K893877) BCI 3025 Reusable Infant Pulse Oximetry Sensor (K901861) BCI 3043 Reusable Universal "Y" Pulse Oximetry Sensor (K893877)

New Device Description:

The BCI® 3178 pediatric pulse oximetry sensor is similar to other existing finger sensors, legally marketed by BCI, Inc. and others. This new finger sensor is designed to work with all BCI pulse oximeters on pediatric patients from 10 to 100 lbs. The sensor is made up of three major parts, the cable with the molded connector, the top part of the shell containing the LEDs and the bottom part of the shell containing the photo detector.

Intended Use:

The BCI® 3178 Pediatric Pulse Oximetry Sensor is a reusable finger sensor that can be used with BCI® pulse oximeter monitors to non-invasively measure oxygen saturation (SpO_2), pulse rate and plethysmographic pulse waves. It is for use with BCI® pulse oximeter monitors or monitors that are licensed to use BCI® pulse oximetry sensors. The BCI® 3178 Pediatric Pulse Oximetry Sensor will provide reliable spot check measurements on patients weighing from 10 to 100 lbs (5 – 45 kg). The sensor is not intended for prolonged use.

Performance Data:

The design of this device utilizes currently available technology found in legally marketed devices. The major difference between the new device and the predicate BCI 3044 pulse oximeter sensor is the smaller size of the new device and . Testing was done to ensure that the BCI® 3178 pediatric pulse oximetry sensor would perform safely and accurately within the environment(s) for which it is to be marketed.

Safety testing was conducted in accordance with the *Reviewer's Guidance for Respiratory Devices, 1993*, and EN 60601-1: 1990. Electrical, mechanical durability, and thermal safety tests have been completed. The results demonstrate that the BCI® 3178 pediatric pulse oximetry sensor is in compliance with the guidelines and standards referenced in the reviewer's guides and that it performs within its specifications and functional requirements.

Testing of device performance included clinical testing of the SpO_2 parameter. Tests on adults showed the sensor to be accurate during desaturation conditions. Additional tests on pediatric subjects (not desaturated) demonstrated the functionality of the sensor over the indicated size range. The results demonstrated that the BCI® 3178 pediatric pulse oximetry sensor performed within its specifications.

The testing described above indicate that there is no functional difference between the operation of the BCI® 3178 pediatric pulse oximetry sensor and the predicate devices. Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Donald Alexander
VP Regulatory Affairs
BCI, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 3 2002

Mr. Donald Alexander
BCI, Inc.
N7 W22025 Johnson Road
Waukesha, WI 53186

Re: K020739
BCI® 3178 Pediatric Pulse Oximetry Sensor
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: March 1, 2002
Received: March 6, 2002

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if Known): K020739

Device Name: BCI® 3178 Pediatric Pulse Oximetry Sensor

Indications For Use:

Intended Use:

The BCI® 3178 Pediatric Pulse Oximetry Sensor is a reusable finger sensor that can be used to non-invasively measure oxygen saturation (SpO_2), pulse rate and plethysmographic pulse waves. It's performance was validated with the BCI® 3304 pulse oximeter. The BCI® 3178 Pediatric Pulse Oximetry Sensor will provide reliable spot check measurements on patients weighing from 10 to 100 lbs (5 – 45 kg). The sensor is not intended for prolonged use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020739

Prescription Use ✓ OR Over-The_Counter Use _____
(Per 21 CFR 801.109)